K090506

MAYFIELD® Infinity XR2 Skull Clamp

510(k) Summary

APR 20 2009

Submitter's name and address:

Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, Ohio 45227 USA

Contact person and telephone number:

Helder A. Sousa
Regulatory Affairs Project Manager
Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, Ohio 45227 USA
Phone: (781) 565-1235
Fax: (781) 238-0645

Date prepared:

February 23rd 2009

Name of device:

Trade Name:	MAYFIELD® Infinity XR2 Skull Clamp
Common Name:	Skull Clamp
Classification Name:	Holder, Head, Neurosurgical (Skull Clamp)
Regulation Number:	21 CFR 882.4460
Product Code:	HBL

Substantial Equivalence:

The MAYFIELD® Infinity XR2 Skull Clamp is substantially equivalent in function and intended use to the MAYFIELD® MR/CT Skull Clamp (K050319) and the MAYFIELD® Infinity Skull Clamp (K051440).

Indications Use:

The MAYFIELD® Infinity XR2 Skull Clamp is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.

In addition, the clamp is indicated for use during utilization of imaging modalities such as intra-operative CT imaging, C-Arm x-ray, and digital subtraction techniques.

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Device Description:

The MAYFIELD® Infinity XR2 Skull Clamp is designed to be a multifunctional, cranial stabilization/fixation device. Its basic configuration delivers standard MAYFIELD Skull Clamp performance, that is, provide rigid skeletal fixation in conjunction with various MAYFIELD Base Units. The MAYFIELD® Infinity XR2 Skull Clamp is suitable for Digital Subtraction Angiography (DSA), Fluoroscopy and CT imaging modalities.

With the use of the optional removable Force Applicator, the user can temporarily detach this component of the clamp prior to scanning; thereby removing a potential source of imaging artifact. Interchangeable components allow the surgeon to tailor the skull clamp and the cranial stabilization equipment to the requirements of their patient's surgical procedure and the use of image-guided surgery systems.

The MAYFIELD® Infinity XR2 Skull Clamp is designed to allow the surgeon freedom in positioning the skull pins for fixation. Avoidance of critical areas of the skull is facilitated by a two-pin rocker arm that swivels 360º degrees. To simplify patient repositioning after pin impingement, the rocker arm can be rotated without adjustment of the Torque Screw force on the single-pin side of the clamp.

Conclusion:

The MAYFIELD® Infinity XR2 Skull Clamp is substantially equivalent to the MAYFIELD® MR/CT Skull Clamp (K050319) and the MAYFIELD® Infinity Skull Clamp (K051440). The MAYFIELD® Infinity XR2 Skull Clamp is similar to the predicate devices in the intended use, the fundamental scientific technology of the device, and does not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Integra Life Sciences Corporation
c/o Mr. Helder A. Sousa
Regulatory Affairs Project Manager
4900 Charlemar Drive, Bldg. A
Cincinnati OH 45227

APR 20 2009

Re: K090506
Trade/Device Name: Mayfield® Infinity XR2 Skull Clamp
Regulation Number: 21 CFR 882.4460
Regulation Name: head, neurosurgical (skull clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: February 23, 2009
Received: February 25, 2009

Dear Mr. Sousa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090506

Indications for Use

510(k) Number (if known):

Device Name: MAYFIELD® Infinity XR2 Skull Clamp

Indications For Use:

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In addition, the clamp is indicated for use during utilization of imaging modalities such as intra-operative CT imaging, C-Arm x-ray, and digital subtraction techniques.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

510(k) Number K090506